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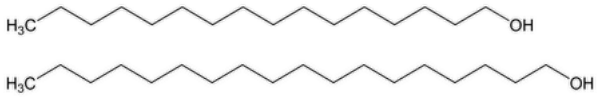
Cetostearyl Alcohol

Change to read:



▲Mixture of cetyl and stearyl alcohols▲ (NF 1-Dec-2023)

CAS RN®: 67762-27-0.

DEFINITION

Cetostearyl Alcohol contains NLT 40.0% of stearyl alcohol ($C_{18}H_{38}O$), and the sum of the stearyl alcohol content and the cetyl alcohol ($C_{16}H_{34}O$) content is NLT 90.0% and NMT 102.0%. It is obtained from sources of vegetable, animal, or synthetic origin.

IDENTIFICATION

• **A. Chromatographic Identity**

Analysis: Proceed as directed in the *Assay*.

Acceptance criteria: The retention times of the major peaks of the *Sample solution*, excluding the solvent and internal standard peaks, correspond to the cetyl alcohol and stearyl alcohol peaks of the *System suitability solution*.

ASSAY

• **Procedure**

Internal standard solution: 1 mg/mL of 1-pentadecanol (internal standard) in ethanol

System suitability solution: Prepare 1 mg/mL each of USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, and USP Oleyl Alcohol RS in the *Internal standard solution*. Heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well.

Standard solution: To match the cetyl alcohol and stearyl alcohol ratio in the test sample, prepare the sum of 2.0 mg/mL of USP Cetyl Alcohol RS and USP Stearyl Alcohol RS in the *Internal standard solution*. Heat the solution in a sealed container in a 50° water bath until cetyl alcohol and stearyl alcohol are dissolved. Allow the solution to cool to room temperature, and mix well.

Sample solution: Prepare 2.0 mg/mL of Cetostearyl Alcohol in the *Internal standard solution*, and heat the solution in a sealed container in a 50° water bath until the cetostearyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.25-mm × 30-m fused-silica capillary; coated with a 0.25-µm layer of phase G7

Temperatures

Detector: 280°

Injection port: 270°

Column: See *Table 1*.

Table 1

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
60	20	180	—
180	10	220	5

Carrier gas: Hydrogen

Flow rate: 2.0 mL/min, constant flow mode

Injection volume: 1 µL

Injection type: Split, split ratio 100:1

Liner: Single taper, low pressure drop liner with deactivated wool

Run time: 15 min

System suitability

Samples:

System suitability solution and *Standard solution*

[NOTE—See *Table 2* for the relative retention times.]

Table 2

Component	Relative Retention Time
1-Pentadecanol (internal standard)	1.00
Cetyl alcohol	1.09
Stearyl alcohol	1.25
Oleyl alcohol	1.28

Suitability requirements

Resolution: NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks, *System suitability solution*

Tailing factor: 0.8–1.8 for the stearyl alcohol and 1-pentadecanol peaks, *Standard solution*

Relative standard deviation: NMT 1%, using the area ratio of stearyl alcohol to 1-pentadecanol, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentages of cetyl alcohol ($C_{16}H_{34}O$) or stearyl alcohol ($C_{18}H_{38}O$) in the portion of Cetostearyl Alcohol taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak response ratio of cetyl alcohol (or stearyl alcohol) to the internal standard from the *Sample solution*

R_S = peak response ratio of cetyl alcohol (or stearyl alcohol) to the internal standard from the *Standard solution*

C_S = concentration of USP Cetyl Alcohol RS (or USP Stearyl Alcohol RS) in the *Standard solution* (mg/mL)

C_U = concentration of Cetostearyl Alcohol in the *Sample solution* (mg/mL)

Acceptance criteria

Stearyl alcohol ($C_{18}H_{38}O$): NLT 40.0%

Sum of stearyl alcohol ($C_{18}H_{38}O$) and cetyl alcohol ($C_{16}H_{34}O$): 90.0%–102.0%

IMPURITIES

• **RESIDUE ON IGNITION ⟨281⟩:** NMT 0.1%, determined on 2 g

Change to read:

• **LIMIT OF RELATED FATTY ALCOHOLS**

Solution A: 1 mg/mL of 1-pentadecanol in ethanol

Resolution solution: Prepare 1 mg/mL each of USP Lauryl Alcohol RS, USP Myristyl Alcohol RS, USP Cetyl Alcohol RS, USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, ▲USP Linoleyl Alcohol RS,▲ (NF 1-Dec-2023) USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS in *Solution A*. Heat the solution in a sealed container in a 50° water bath until all fatty alcohols are dissolved. Allow the solution to cool to room temperature, and mix well. Dilute the solution with ethanol to obtain a solution containing 0.05 mg/mL each of USP Lauryl Alcohol RS, USP Myristyl Alcohol RS, USP Cetyl Alcohol RS, 1-pentadecanol, USP Stearyl Alcohol RS, USP Oleyl Alcohol RS, ▲USP Linoleyl Alcohol RS,▲ (NF 1-Dec-2023) USP Linolenyl Alcohol RS, and USP Arachidyl Alcohol RS.

Sample solution: 1 mg/mL of Cetostearyl Alcohol in ethanol. Heat the solution in a sealed container in a 50° water bath until the cetostearyl alcohol is dissolved. Allow the solution to cool to room temperature, and mix well.

Chromatographic system: Proceed as directed in the *Assay*, except for the *Injection type*.

Injection type: Split; split ratio 5:1

System suitability

Sample: *Resolution solution*

[NOTE— ▲The relative retention times in *Table 3* are provided as information that could aid in peak assignment.▲ (NF 1-Dec-2023)]

Table 3

Component	▲Number of Double Bonds▲ (NF 1-Dec-2023)	Relative Retention Time
Lauryl alcohol	▲0▲ (NF 1-Dec-2023)	0.79
Myristyl alcohol	▲0▲ (NF 1-Dec-2023)	0.93
1-Pentadecanol	▲0▲ (NF 1-Dec-2023)	1.00
Cetyl alcohol	▲0▲ (NF 1-Dec-2023)	1.09
Stearyl alcohol	▲0▲ (NF 1-Dec-2023)	1.25
Oleyl alcohol	▲1▲ (NF 1-Dec-2023)	1.28
▲Linoleyl alcohol	2	1.30▲ (NF 1-Dec-2023)
Linolenyl alcohol	▲3▲ (NF 1-Dec-2023)	1.36
Arachidyl alcohol	▲0▲ (NF 1-Dec-2023)	1.44

Suitability requirement

Resolution: NLT 15 between the myristyl alcohol and 1-pentadecanol peaks; NLT 30 between the cetyl alcohol and stearyl alcohol peaks; NLT 2.0 between the stearyl alcohol and oleyl alcohol peaks

Analysis

Samples: *Resolution solution* and *Sample solution*

Identify each related fatty alcohol peak in the *Sample solution* based on that in the *Resolution solution*.

Calculate the percentage of each related fatty alcohol or any ▲unidentified▲ (NF 1-Dec-2023) impurity in the portion of Cetostearyl Alcohol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of each related fatty alcohol (or any ▲unidentified▲ (NF 1-Dec-2023) impurity) from the *Sample solution*

r_T = sum of all the peak responses excluding peak responses due to solvent from the *Sample solution*

Acceptance criteria: Disregard peaks that are less than 0.05% for any ▲unidentified▲ (NF 1-Dec-2023) impurities, and any peaks due to solvent.

Sum of ▲unidentified▲ (NF 1-Dec-2023) impurities: NMT 1%

▲Related unsaturated fatty alcohols: NMT 4%▲ (NF 1-Dec-2023)

Sum of related fatty alcohols and **▲unidentified▲ (NF 1-Dec-2023) impurities:** NMT 10.0%

SPECIFIC TESTS

- **FATS AND FIXED OILS** ⟨401⟩, *Acid Value*: NMT 2
- **FATS AND FIXED OILS** ⟨401⟩, *Hydroxyl Value*: 208–228

Delete the following:

- ▲**FATS AND FIXED OILS** ⟨401⟩, *Iodine Value*▲ (NF 1-Dec-2023)
- **WATER DETERMINATION** ⟨921⟩, *Method I*: NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **Labeling:** Label it to indicate whether it is derived from vegetable, animal, or synthetic sources.

Change to read:

• **USP Reference Standards** (11)

USP Arachidyl Alcohol RS
USP Cetyl Alcohol RS
USP Lauryl Alcohol RS
▲USP Linoleyl Alcohol RS▲ (NF 1-Dec-2023)
USP Linolenyl Alcohol RS
USP Myristyl Alcohol RS
USP Oleyl Alcohol RS
USP Stearyl Alcohol RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CETOSTEARYL ALCOHOL	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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